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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/693,042

10/24/2003

Nurit Kalderon

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7590
Dr. NURIT KALDERON
APT. 6J
30 RIVER ROAD
NEW YORK, NY 10044

01/24/2008

EXAMINER

WEGERT, SANDRA L

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

01/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/693,042	KALDERON, NURIT	
	Examiner	Art Unit	
	SANDRA WEGERT	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8-10, 15-17 and 22-24 is/are rejected.
- 7) ☒ Claim(s) 4-7, 11-14, 18-21, 25-28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/22/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The Information Disclosure Statement and the Amendment, received 22 October 2007, have been entered. Claims 1-4, 8-11, 15-18 and 22-25 have been amended. Claims 1-28 are under examination.

Withdrawn Objections and/or Rejections

Claim Rejections - 35 USC § 112, second paragraph, indefiniteness.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

The rejection of Claims 4, 11, 18 and 25 for containing the trademark/trade names *Betaseron* and *Avonex* is *withdrawn*. It is clear that *Betaseron* and *Avonex* refer to brands of beta interferon, as do newly-added names *Rebif* and *Cinnovex* (22 October 2007).

The rejection of Claims 4, 11, 18 and 25 for lacking proper antecedent basis for the words *Betaseron* and *Avonex*, is *withdrawn*. *Betaseron* and *Avonex* are brand names of beta interferon; therefore they have antecedent basis in the *beta interferon* recited in independent claims.

The rejection of Claims 6, 7, 13, 14, 20 and 21 for reciting the phrase "or later," is *withdrawn*. As argued by applicants (22 October 2007, Remarks, p. 7), the phrase embraces time points any time after administration, including many years after injury, as such time points are

Art Unit: 1647

enabled by the instant Specification.

Claim Rejections - 35 USC § 112, first paragraph - Enablement.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of Claims 1-28 under 35 USC 112, first paragraph, for lack of enablement is *withdrawn* based on Applicants' arguments (Remarks, pp. 7, 9 and 10). Applicants have argued that the chronic secondary inflammation that results from spinal cord injury can be treated effectively using beta interferon. This chronic inflammation is evidenced by high chronic levels of VCAM-1 (see Figure 5 of the instant disclosure, for example).

In addition, the rejection of claims 8 and 9-14 for reciting or embracing the term "preventing," is *withdrawn*. Applicants removed the word "preventing" from claim 8, but replaced it with a similar term, as discussed below.

New/Maintained Objections and/or Rejections

Claim Objections-

Claims 4-7, 11-14, 18-21 and 25-28 are objected to for depending from a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections-- 35 USC § 112, first paragraph - Written Description

Claims 1-3, 8-10, 15-17 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The *new matter* added to the claims that is not supported by the disclosure is: the word "biosimilar."

Claim Rejections - 35 USC § 112, first paragraph - Enablement.

The specification does not disclose halting the progressive chronic inflammation, as recited in claim 8 and embraced by claims 9-14. The term "halt" is interpreted as meaning that the chronic inflammatory activity is *completely* stopped. As defined in the Merriam-Webster Dictionary (<http://www.merriam-webster.com>, accessed online 10 January 2008), *halt* means "to cease" or "to bring to a stop." Undue experimentation would be required of the skilled artisan to determine the quantity of β -interferon to be administered, the best route of administration, the duration of treatment, and any possible side-effects to put a stop completely to all chronic inflammatory processes.

Art Unit: 1647

Conclusion

Claims 1-3, 8-10, 15-17 and 22-24 are rejected. Claims 4-7, 11-14, 18-21 and 25-28 are objected to.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Manjunath Rao, can be reached at (571) 272-0939.

Art Unit: 1647

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

/SLW/

9 January 2008

/Manjunath N. Rao, /

Supervisory Patent Examiner, Art Unit 1647